

REMARKS

Claims 1-5 are pending in this application. Claims 6-8 were previously canceled in response to the Restriction Requirement issued by the Examiner. No claims have been amended. No new claims have been added.

Claims 1-5 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of co-pending application numbers 10/385,597 and 10/955,276. The Examiner has acknowledged that Applicants will address this ground of rejection when there is allowable subject matter in these co-pending applications.

Claims 1-5 have been rejected under 35 U.S.C. § 103(a) as being obvious over Kovacs et al., in view of Smallwood. Applicants believe that this ground of rejection is not well founded and should be withdrawn for the following reasons.

Kovacs relates to a trimonthly oral contraceptive regimen in which estrogen and progestin are administered daily for 84 consecutive days without a hormone-free period. There is no teaching in Kovacs of transdermal administration, much less an extended transdermal contraceptive regimen.

Smallwood likewise fails to teach or even suggest an extended transdermal contraceptive regimen. Smallwood administers contraceptive hormones transdermally for only the standard 21-day regimen, followed by a hormone-free period of 7 days.

The Examiner argues that it would have been *prima facie* obvious to substitute the contraceptive composition taught by Kovacs with the ethinyl estradiol/norelgestromin composition disclosed by Smallwood. Contrary to the Examiner's assertion, a person skilled in the art would not have a reasonable expectation that such a substitution would result in an extended regimen providing enhanced cycle control and enhanced continuation and satisfaction rates. Such a substitution would require the skilled person not only to change the hormone composition and administration route of Kovacs, but also convert the standard 21-day transdermal regimen of Smallwood to an extended 3-month transdermal regimen. There is no teaching or suggestion in Smallwood that his regimen would provide acceptable cycle control and be well tolerated if it were administered as an extended regimen. To the contrary, a skilled person would not be motivated to convert the monthly regimen of Smallwood to an extended regimen as taught by Kovacs because, as acknowledged by the Examiner, half of the women discontinued the extended contraceptive regimen taught by Kovacs due to breakthrough bleeding.

The claims recite certain features of the invention that distinguish it over the prior art, including enhanced bleeding control and enhanced continuation and satisfaction rates that are characterized by longer median time-to-first bleed, fewer mean bleeding days and reduced median incidence of headaches. As these features further define the claimed method of contraception, applicants disagree with the Examiner's assertion that they are entitled to little patentable weight. Applicants also disagree with the assertion that these limitations are inherent. A person skilled in the art would not predict that converting standard monthly transdermal administration of a combination of contraceptive hormones to extended administration would result in the enhanced cycle control and continuation and satisfaction rates of the claimed invention. This was only established by the Phase II clinical trial conducted by applicants, the results of which are reported in the specification.

In view of the foregoing applicants believe that claims 1-5 patentably distinguish over the cited art and request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

Applicants hereby petition for a one-month extension of time to respond to the outstanding Office Action. Please charge the fee required for this extension, and any other fees that may be required, to Deposit Account No. 10-0750/PRD0007CIP/JSK..

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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